

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PP17767.003	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/00657	International filing date (day/month/year) 08 January 2003 (08.01.2003)	Priority date (day/month/year) 08 January 2002 (08.01.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): C12Q 1/68; A01N 43/04; C07H 21/04; A61K 31/07 and US Cl.: 435/325, 375, 5, 6; 536/24.5; 514/44, 2; 424/130.1		
Applicant CHIRON CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 28 July 2003 (28.07.2003)	Date of completion of this report 28 October 2004 (28.10.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Terra C. Gibbs Telephone No. (571) 272-0564

Form PCT/IPEA/409 (cover sheet) (July 1998)

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed.☒ the description:

pages 1-120 _____ as originally filed

pages NONE _____, filed with the demand

pages NONE _____, filed with the letter of _____.

☒ the claims:

pages 121-123 _____ as originally filed

pages NONE _____, as amended (together with any statement) under Article 19

pages NONE _____, filed with the demand

pages NONE _____, filed with the letter of _____.

☐ the drawings:

pages NONE _____, as originally filed

pages NONE _____, filed with the demand

pages NONE _____, filed with the letter of _____.

☒ the sequence listing part of the description:

pages 1-126 _____, as originally filed

pages NONE _____, filed with the demand

pages NONE _____, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☒ contained in the international application in printed form.☒ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. ☐ The amendments have resulted in the cancellation of:☐ the description, pages NONE☐ the claims, Nos. NONE☐ the drawings, sheets/fig NONE5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-30</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-30</u>	NO
Industrial Applicability (IA)	Claims <u>1-30</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-30 meet industrial applicability as defined by PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Claims 1-30 lack novelty under PCT Article 33(2)-(3) as being anticipated by Hillman et al. It is noted that DKFZ is also known as VMP, as disclosed in Applicants disclosure at Figure 5 and page 7, last line). Hillman et al. disclose compositions comprising vesicle membrane protein-like proteins (VMP). The vesicle membrane protein-like proteins disclosed by Hillman et al. are also known as DKFZ. Hillman et al. also disclose methods for treating and preventing disorders associated with the expression of VMP using proteins, nucleic acids, antisense, antibodies or any other molecules which decrease the effect of VMP (see Hillman et al. Abstract and page 11, last paragraph and page 12). Hillman et al. further teach a method for detecting a cancerous cell comprising detecting a level of DKFZ in a test sample (see page 5, fourth paragraph). Hillman et al. also teach an isolated polynucleotide comprising at least 15 contiguous nucleotides of SEQ ID NO:1 of the instant invention.

Claims 1-8 and 17-19 lack an inventive step under PCT Article 33(3) as being obvious over Hillman et al. in view of Vaccaro et al. and Dusetti et al. Hillman et al. disclose compositions comprising vesicle membrane protein-like proteins (VMP). Hillman et al. also disclose methods for treating and preventing disorders associated with the expression of VMP, using molecules which decrease the effect of VMP. Vaccaro et al. teach further studies are needed to lead to a better understanding of the function of VMP expression. Dusetti et al. teach further studies leading to a better understanding of the function of VMP expression is warranted.

It would have been obvious to one of ordinary skill in the art to devise a method for inhibiting a cancerous phenotype of a cell comprising administering an agent which inhibits DKFZ activity because Hillman et al. disclose such methods. One of ordinary skill in the art would have been motivated to inhibit a cancerous of a cell comprising administering an agent which inhibits DKFZ activity because the teachings of Vaccaro et al. and Dusetti et al. provide clear motivation for one skilled in the art to inhibit the expression of VMP to understand its function in vivo.

The invention would have been obvious to one of ordinary skill in the art at the time of filing of the instant application.

----- NEW CITATIONS -----